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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,803	09/04/2003	Warner C. Greene	UCAL-283	7086

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,803	GREENE ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *16-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/6/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received April 27, 2006.

Election/Restrictions

Applicant's election of group I, claims 1-15, with traverse in the response to the restriction requirement on April 27, 2006 has been acknowledged. Applicants arguments regarding restriction requirement have been fully considered but fail to persuade. Applicant argues that all of the claims in groups I-IV require use of retroviral virion having a chimeric viral protein and a search to identify relevant art to the claims of group I with respect to the use of a chimeric viral protein would also identify art relevant to the claims of groups II-IV and also group V. Applicant also argues that claims of group VIII directed to the kit should be examined with groups containing claims directed to the compositions present in the kits.

As set forth in the restriction requirement, the method for detecting fusion of an enveloped retrovirus to a target cell of group I, the method for identifying an agent that modulates fusion of HIV virion to a target cell of group II, the method for identifying a viral envelope protein that facilitates viral fusion to a target cell of group III, and a method according to the method of group III further comprising contacting the target cell with a candidate agent that facilitates viral fusion to a target cell of group IV do not overlap in scope. A search for one method does not reveal literature regarding the other methods. For example, the reference by Muthumani et al. (cited in the IDS) reveals the literature regarding the method of group I regarding detecting fusion of an enveloped retrovirus to a target cell but the same reference does not reveal the literature regarding the method for identifying an agent that modulates fusion of

HIV virion to a target cell of group II. An additional search would be required in order to find literature regarding a method for identifying or screening agents that modulate fusion of HIV virion to a target cell of group II. The method of group II uses the reagents that are not used by the method of group I, such as the agents that modulate the fusion of HIV virion to a target cell. Thus, the restriction is deemed proper and is made FINAL.

Claims 1-31 are pending. Claims 16-31 are withdrawn because they are drawn to a non-elected invention. Claims 1-15 are examined on the merits.

Priority

Acknowledgment is made of a claim for priority to a provisional application, 60/409,401.

Information Disclosure Statement

The Information Disclosure Statement received May 6, 2004 has been considered and attached to this Office Action.

Claim Objections

Claim 6 objected to because of the following informalities: The substrate "CCF2" should be spelled out before the first use of the abbreviation.

There is a typographical error in claims 11 and 15, "psuedotyped".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muthumani et al. (cited in the IDS) in view of Zlokarnik et al., (Science, 1998).

Claims are drawn to a method for detecting fusion of enveloped retrovirus to a target cell comprising contacting a target cell with an enveloped retroviral chimeric virion containing Viral protein R from HIV operably linked to a reporter polypeptide beta-lactamase (BlaM) through a spacer peptide. Beta-lactamase provides a detectable signal by cleaving CCF2 substrate. The presence of detectable signal indicates the virion has fused with the target cell.

Muthumani et al. teach a method for detecting fusion of enveloped retrovirus such as HIV, wherein the chimeric virion contains Viral protein R from HIV operably linked to a reporter protein which is a Green Fluorescent Protein (GFP), see the entire document. The detection of fluorescence from Vpr-GFP fusion protein present in the virion of Muthumani et al., indicates the virion has fused with the target cell. Both constructs, the Muthumanis' Vpr-GFP and the instantly claimed construct, the Vpr and BlaM, were generated using molecular biology cloning techniques known in the art. The person of the ordinary skill in the art would have inserted a spacer peptide joining the Vpr and BlaM for construct purposes, thus the spacer peptide (in the instant claims 10 and 14) is not considered to be limiting.

Muhatmani et al., does not teach using beta-lactamase and CCR2 substrate as a detection signal for their virion-based fusion assay. Zlokarnik et al., teach using beta-lactamase as a reporter polypeptide to measure gene expression in single live mammalian cell (see the entire document). The substrate for beta-lactamase is CCF2.

It would have been obvious for the person of the ordinary skill in the art to substitute the GFP reporter polypeptide in the virion-based fusion assay taught by Muhatmani et al., with the beta-lactamase reporter polypeptide using the CCF2 substrate taught by Zlokarnik et al.

One would have been motivated to substitute the GFP reporter polypeptide in the virion-based fusion assay taught by Muhatmani et al., with the beta-lactamase reporter polypeptide using the CCF2 substrate taught by Zlokarnik et al. because Zlokarnik et al. teach that beta-lactamase reporter system can facilitate many applications such as for example genetically tagging transfected mammalian cells (see page 88). One would have had a reasonable expectation of success to practice Muhatmanis' virion-based assay using beta-lactamase reporter polypeptide and the CCF2 substrate instead of using GFP as a reporter polypeptide because Zlokarnik has shown that beta-lactamase reporter polypeptide with the CCF2 substrate have been successfully used as detection signal in target cells. Therefore at the time of the instant invention, the claims would have been obvious over Muhatmanis' virion-based assay and Zlokarnik's beta-lactamase reporter polypeptide.

Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muthumani et al. (cited in the IDS) in view of Zlokarnik et al., (Science, 1998) as applied to claim above, and further in view of Miyanohara et al. (US Patent 5,739,018).

The claims are drawn to a method for detecting fusion of an enveloped retrovirus to a target cell, wherein the retroviral virion is a pseudotyped virion, and wherein the envelope protein of the pseudotyped virion is not endogenous to the retroviral virion.

Applicant defines a "pseudotyped virion" as a virion having an envelope protein that is provided in trans to the other viral proteins for production of the viral particle, usually a non-endogenous viral envelope protein (e.g., is other than the naturally-occurring envelope protein of the virion). For example, if the HIV is pseudotyped with VSV-G (Vesicular Stomatis Viral protein G).

Miyanohara teach a retroviral vector pseuotyped with VSV-G (see column 2, lines 12-18, and column 9, lines 62-67).

It would have been obvious for one of the ordinary skill in the art to use a pseudotyped virion with the beta-lactamase reporter polypeptide and the CCF2 substrate in the method for detecting fusion of the enveloped retrovirus to a target cell. One would have been motivated to use a pseudotyped virion in the method for detecting fusion of the enveloped retrovirus to a target cell because Miyanohara teach that pseudotyped retroviral virions are useful in transformation of target cells (see column 1, lines 65-67). One would have a reasonable expectation of success to use pseudotyped retroviral virions in the method for detecting fusion of the enveloped retrovirus to a target cell because those pseudotyped retroviral virions have the ability to fuse with the target cells just like the non-pseudotyped virions. Therefore at the time of the instant invention, the claims would have been obvious over Muhatmanis' virion-based assay Zlokarnik's beta-lactamase reporter polypeptide, and Miyanohara pseudotyped retroviral virions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

7/5/06

Stacy B. Chen 7/5/06

Stacy B. Chen
Primary Examiner